THE UNIVERSITY OF TEXAS AT EL PASO

UTEP Institutional Review Board
Kelly Hall, 4th floor
IRB@utep.edu

IRB Unanticipated Problem–Adverse Event Report Form

INVESTIGATOR INFORMATION

Principal Investigator (Last name, First)			
Project Title			
IRB Protocol #			
Email		**Department**	
Phone		**School or College**	

Co-Investigator (if applicable)			
Email		**Phone**	

Faculty Advisor (if not the PI)			
Email		**Phone**	

Funding Agency (if applicable)	

SECTION 1: CRITERIA — Does the event being reported meet the following criteria?

1. An unexpected (in nature, severity, or frequency) incident, experience, or outcome, given the procedures described in the IRB-approved research protocol and informed consent document; and given the characteristics of the research subject population.	☐ **YES**	☐ **NO**
2. An incident, experience, or outcome related or possibly related to participation in the research. ("Possibly related" means that a *reasonable* possibility exists that the incident, experience, or outcome may have been caused by research procedures.)	☐ **YES**	☐ **NO**
3. An incident, experience, or outcome suggesting that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than previously realized or anticipated.	☐ **YES**	☐ **NO**

If you answered "YES" to all three criteria, or a Serious Adverse Event has occurred, complete this form and return it to the IRB according to the timeline indicated in the Unexpected Problem–Adverse Event policy.

SECTION 2: URGENCY AND PROBLEM/EVENT DESCRIPTION

1. Do you believe this event warrants **immediate or urgent attention** by the IRB and perhaps others? If ***yes***, provide a detailed description of the unanticipated problem, adverse event, incident, experience, or outcome.

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SECTION 3: CONSENT AND PARTICIPANTS

1. Is the risk of this unanticipated problem explained in the current consent form?	☐ **YES**	☐ **NO**
2. Should the consent form or any portion of this study be revised as a result? If "Yes" please describe modifications in Section 4.	☐ **YES**	☐ **NO**

3. Will currently enrolled participants be notified of this event? If yes, please describe method of notification.

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SECTION 4: CORRECTIVE MEASURES

1. Describe any corrective actions that have been taken or are proposed in response to the unanticipated problem. If actions require changes to the protocol or consent form, fill out and attach the Modification Form with corresponding documents.

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INVESTIGATOR VERIFICATION STATEMENT

By submitting this form, I certify all information is accurate and this project has been conducted in strict accordance with federal regulations and UTEP policies governing human subject research.

Signature of Principal Investigator _____ _____
Date (mm/dd/yy)

Signature of Co-Investigator (if applicable) _____ _____
Date (mm/dd/yy)

Signature of Faculty Advisor (if PI is not Faculty) _____ _____
Date (mm/dd/yy)